

the manufacturer's choice, type examination, and verification reports prepared to EC medical device requirements.

(c) Based on the determination of equivalence in light of the experience gained, the product evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies, inadequacies, or incompleteness in a product evaluation report, or other specific evidence of serious concern in relation to product safety, performance, or quality. In such cases, the importing party may request clarification from the exporting party which may lead to a request for a reevaluation. The parties will endeavor to respond to requests for clarification in a timely manner. Endorsement remains the responsibility of the importing party.

**§ 26.43 Transmission of quality system evaluation reports.**

Quality system evaluation reports covered by § 26.41 concerning products covered by this subpart shall be transmitted to the importing party within 60-calendar days of a request by the importing party. Should a new inspection be requested, the time period shall be extended by an additional 30-calendar days. A party may request a new inspection, for cause, identified to the other party. If the exporting party cannot perform an inspection within a specified period of time, the importing party may perform an inspection on its own.

**§ 26.44 Transmission of product evaluation reports.**

Transmission of product evaluation reports will take place according to the importing party's specified procedures.

**§ 26.45 Monitoring continued equivalence.**

Monitoring activities will be carried out in accordance with § 26.69.

**§ 26.46 Listing of additional CAB's.**

(a) During the operational period, additional conformity assessment bodies (CAB's) will be considered for equivalence

using the procedures and criteria described in §§ 26.36, 26.37, and 26.39, taking into account the level of confidence gained in the overall regulatory system of the other party.

(b) Once a designating authority considers that such CAB's, having undergone the procedures of §§ 26.36, 26.37, and 26.39, may be determined to be equivalent, it will then designate those bodies on an annual basis. Such procedures satisfy the procedures of § 26.66(a) and (b).

(c) Following such annual designations, the procedures for confirmation of CAB's under § 26.66(c) and (d) shall apply.

**§ 26.47 Role and composition of the Joint Sectoral Committee.**

(a) The Joint Sectoral Committee for this subpart is set up to monitor the activities under both the transitional and operational phases of this subpart.

(b) The Joint Sectoral Committee will be cochaired by a representative of the Food and Drug Administration (FDA) for the United States and a representative of the European Community (EC) who will each have one vote. Decisions will be taken by unanimous consent.

(c) The Joint Sectoral Committee's functions will include:

(1) Making a joint assessment of the equivalence of conformity assessment bodies (CAB's);

(2) Developing and maintaining the list of equivalent CAB's, including any limitation in terms of their scope of activities and communicating the list to all authorities and the Joint Committee described in subpart C of this part;

(3) Providing a forum to discuss issues relating to this subpart, including concerns that a CAB may no longer be equivalent and opportunity to review product coverage; and

(4) Consideration of the issue of suspension.

**§ 26.48 Harmonization.**

During both the transitional and operational phases of this subpart, both parties intend to continue to participate in the activities of the Global Harmonization Task Force (GHTF) and utilize the results of those activities to

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the extent possible. Such participation involves developing and reviewing documents developed by the GHTF and jointly determining whether they are applicable to the implementation of this subpart.

### § 26.49 Regulatory cooperation.

(a) The parties and authorities shall inform and consult with one another, as permitted by law, of proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

(b) The parties shall notify each other in writing of any changes to Appendix A of this subpart.

### § 26.50 Alert system and exchange of postmarket vigilance reports.

(a) An alert system will be set up during the transition period and maintained thereafter by which the parties will notify each other when there is an immediate danger to public health. Elements of such a system will be described in an Appendix F of this subpart. As part of that system, each party shall notify the other party of any confirmed problem reports, corrective actions, or recalls. These reports are regarded as part of ongoing investigations.

(b) Contact points will be agreed between both parties to permit authorities to be made aware with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

#### APPENDIX A TO SUBPART B OF PART 26— RELEVANT LEGISLATION, REGULATIONS, AND PROCEDURES.

1. For the European Community (EC) the following legislation applies to § 26.42(a) of this subpart:

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036.]

- a. Council Directive 90/385/EEC of 20 June 1990 on active implantable medical devices OJ No. L 189, 20.7. 1990, p. 17. Conformity assessment procedures.  
Annex 2 (with the exception of section 4)

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- Annex 4
- Annex 5
- b. Council Directive 93/42/EEC of 14 June 1993 on Medical Devices OJ No. L 169, 12.7.1993, p.1. Conformity assessment procedures.  
Annex 2 (with the exception of section 4)
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2. For the United States, the following legislation applies to § 26.32(a):

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents may be viewed on FDA's Internet web site at <http://www.fda.gov>.]

- a. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq.*
- b. The Public Health Service Act, 42 U.S.C. 201 *et seq.*
- c. Regulations of the United States Food and Drug Administration found at 21 CFR, in particular, Parts 800 to 1299.
- d. Medical Devices; Third Party Review of Selected Premarket Notifications; Pilot Program, 61 FR 14789–14796 (April 3, 1996).
- e. Draft Guidance Document on Accredited Persons Program, 63 FR 28392 (May 22, 1998).
- f. Draft Guidance for Staff, Industry and Third Parties, Third Party Programs under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA), 63 FR 36240 (July 2, 1998).
- g. Guidance Document on Use of Standards, 63 FR 9561 (February 25, 1998).

#### APPENDIX B TO SUBPART B OF PART 26— SCOPE OF PRODUCT COVERAGE

1. Initial Coverage of the Transition Period  
Upon entry into force of this subpart as described in § 26.80 (it is understood that the date of entry into force will not occur prior to June 1, 1998, unless the parties decide otherwise), products qualifying for the transitional arrangements under this subpart include:

- a. All Class I products requiring premarket evaluations in the United States—see Table 1.
- b. Those Class II products listed in Table 2.

#### 2. During the Transition Period

The parties will jointly identify additional product groups, including their related accessories, in line with their respective priorities as follows:

- a. Those for which review may be based primarily on written guidance which the parties will use their best efforts to prepare expeditiously; and